## Remarks

Claims 1, 19 and 23 have been amended to delete the prodrugs of Formula I, which are now claimed in new claims 26-28. New claims 29 and 30 claim ester derivatives of the compounds of formula I, which are prodrugs, and are supported by the disclosure on page 21, lines 21-24, of the specification. With the amendment to claims 1 and 19. Applicants submit these claims now clearly define metabolites of Formula I, (and not of their prodrugs) such that the rejection under 35 USC §112, second paragraph, is overcome.

Restriction Requirement

Applicants affirm the election, with traverse, of Group I, claims 1-7 and 19- 25, drawn to products of Formula I. New claims 26-30 fall within the scope of the elected subject matter. Applicants request that claims 8-18, drawn to a method of treating and preventing various diseases using products of Formula I, be rejoined once allowable subject matter within Group 1 has been identified.

Rejections Under 35 USC§112

Applicants traverse the rejection of claims 1-7 and 19-25 under 35 USC §112, first paragraph, based on the allegation that the specification does not provide an enabling disclosure for making prodrugs of the compounds of Formula I. Applicants submit that once the active compounds of Formula I have been identified, the synthesis of prodrugs from these compounds is routine for one of ordinary skill in the art. No evidence has been presented to the contrary.

In providing the compounds of Formula I, applicants have identified components which are active as kinase inhibitors. By incorporating the publications cited on page 22 of the specification by reference, the specification provides numerous ways to modify these compounds to form prodrugs which can be metabolized. To identify effective and preferred prodrugs is a matter of routine testing, performed by one skilled in the art on a day to day basis. No evidence has been presented to the contrary.

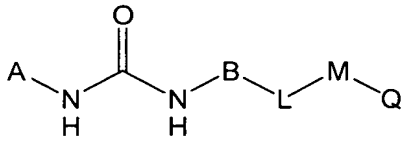
The enablement requirement, "is satisfied if, given what they [, those of ordinary skill in the art,] already know, the specification teaches those in the art enough that they can make

and use the claimed invention without 'undue experimentation." See *Amgen v Hoechst Marion Roussel*, 314 F.2d 1313, 65 USPQ2d 1385 (Fed. Cir. 2003). The specification teaches those skilled in the art how to modify the compounds of formula I to form potential prodrugs. To identify effective or preferred prodrugs from applicants' disclosure would be routine for those of ordinary skill in the art as demonstrated in the textbook by Wolff cited by the examiner. The textbook describes an example of a protocol to identify suitable prodrugs, which is no more than a routine test. To satisfy the statute, a "considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

Explicitly providing an example of a prodrug is not necessary to enable the claims. See, for example, *In re Howarth,* 654 F.2d 105, 210 U.S.P.Q. 689 (CCPA 1981) ("An inventor need not ... explain every detail since he is speaking to those skilled in the art."); *In re Gay*, 309 F.2d 769, 774, 135 U.S.P.Q 311 (CCPA 1962) ("Not every last detail is to be described, else patent specifications would turn into production specifications, which they were never intended to be.") There is no requirement that an applicant provide any working examples of the prodrugs claimed. See, for example, *In re Angstadt*, 537 F.2d at 502-03, 190 USPQ 214 (CCPA 1976) (deciding that applicants "are *not* required to disclose *every* species encompassed by their claims even in an unpredictable art"); *Utter v Higara*, 845 F.2d at 998-99, 6 USPQ2d 1714 (Fed. Cir. 1988) (holding that a specification may, within the meaning of Section 112, Para. 1, enable a broadly claimed invention without describing all species that claim encompasses). The MPEP also agrees by stating that "compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed." See MPEP § 2164.02.

No evidence has been presented which would demonstrate that the guidance provided by the specification is inadequate to enable the manufacture and use of the prodrugs of the compounds of Formula I. The appellants have provided more than adequate guidance to enable the claimed prodrugs

Applicants also traverse the rejection of claims 1-7 and 19-25 under 35 USC 112, first paragraph as allegedly failing to comply with the written description requirement. More particularly, it is alleged that claims 1 and 19 do not contain a complete generic formula. Each of the variables within Formula I, shown below,




is clearly defined by conventional language in the claims and specification so as to satisfy the written description requirement. The variables A, B, L, M and Q are precisely defined structures. No ambiguities have been identified in any of the species recited. Applicants have also satisfied the requirements set forth in MPEP §2163 by disclosing "relevant identifying characteristics," of the compounds of Formula I. There is no need to provide any species of the compounds of formula I since the scope of the definitions for variables A, B, L, M and Q is clear.

The examiner's reference to functional definitions within the claims is not understood and identification of these definitions is respectfully requested . It is believed all features of the compounds claimed are defined structurally.

For the reasons discussed above, Applicants submit that all claims meet the requirements of 35 U.S.C. §112, first and second paragraphs and the rejections under this statute should be withdrawn.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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